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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,970	12/28/2000	Isao Karube	201487/1030	1866

7590 09/23/2003

Michael L Goldman
Nixon Peabody
Clinton Square
PO Box 31051
Rochester, NY 14603

EXAMINER

AKHAVAN, RAMIN

ART UNIT	PAPER NUMBER
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1636

24

DATE MAILED: 09/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

FILE

Office Action Summary

Application No.

09/623,970

Applicant(s)

KARUBE ET AL.

Examiner

Ramin (Ray) Akhavan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07/28/03.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 7-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 22-24 is/are rejected.
- 7) ☒ Claim(s) 6 and 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☒ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Continued Prosecution Application

The request filed on 06/09/2003 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09623970 is acceptable and a CPA has been established. An action on the CPA follows.

Claims 7-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9 filed on 06/22/01.

Claim Objections

Claims 6 and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 22-24 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Applicant has not presented any arguments different from those already presented in paper no. 15. As paper no. 18 indicated, the rejection of claims is not overcome by Applicant's amendment or arguments. As previously discussed (Paper no. 18) the claims encompass a very large number of species and the specification discloses only one species. Applicant is claiming a genus of membrane-disrupting reagents as well as a genus of stimuli that effectuate temporary and partial membrane disruption. The written description requirement for a claimed genus may be satisfied by sufficient description of a representative number of species by actual reduction to practice, reduction to drawings or by disclosure relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure or by a combination of such identifying characteristics sufficient to show applicant was in possession of the claimed genus.

There is no teaching of a common structure-function element amongst all the species the claims (1 and 22-24) encompass and the disclosed species; the written description requirement is not obviated by merely disclosing a method to assay whether the various species or combination of species function or would function the same way as the disclosed species. Such an assay may obviate an enablement rejection, but not a written description rejection.

Furthermore, the declaration under 37 CFR 1.132 filed July 28, 2003 is insufficient to overcome the rejection of claims 1 and 22-24 based upon §112 ¶1 as set forth in the last Office action because: although applicant provides detailed information on an agent for sensitizing PC12 rat pheochromocytoma cell membranes to sonication, the end result is that a single species has been described where applicant is claiming a genus. The declaration outlines results from an experiment using Merocyanine 540 as a sonosensitizer allowing cell penetration subsequent to

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sonication. Notably the specification does not remotely contain the level of detail contained in the declaration, viz., a membrane disrupting agent – Merocyanine 540 and the source of stimuli – sonication. In fact the only reference as to this combination of a reagent and a stimuli is a cursory reference that “[A]ny combination may be used as long as it can perforate the membrane in a controllable manner without completely destroying the membrane.” Spec. at 9 ¶1.

Furthermore the disclosure generally recites virtually every possible stimulus that could be used for the stated purpose of the invention, whether alone or in combination. *Id.* It is against this backdrop that the specification recites ultrasonic soundwaves as a possible stimulus. However, one of ordinary skill in the art would realize that many different parameters would effect whether sonication is effective or whether the membrane is irreversibly sheared (e.g. types of cells used, frequency of soundwaves, duration of bursts and type of membrane-disrupting reagent used).

In light of the fact that there is virtually nothing in the specification with regard to using the particular reagent and stimulus as disclosed in the declaration and that even if there were such information disclosed, it would amount to a single example where a genus is claimed. In addition, there is nothing in the disclosed example in the declaration, which would allow the skilled artisan to envision other members of the claimed genus, i.e. a combination of an antibody and a virus or a lipid and electromagnetic waves, etc. It must be considered that applicant has not disclosed a representative number of species sufficient to convince the skilled artisan that applicant is in possession of the claimed genus.

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Conclusion

All claims are drawn to the same invention claimed in the parent application prior to the filing of this Continued Prosecution Application under 37 CFR 1.53(d) and could have been finally rejected on the grounds and art of record in the next Office action. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing under 37 CFR 1.53(d). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Akhavan whose telephone number is 703-305-4454. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

RA


DAVID GUZO
PRIMARY EXAMINER